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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/23/2003

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,187

Applicant(s)

SHEFFIELD ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21 and 27-31, drawn to an isolated polynucleotide, vectors and host cells comprising the polynucleotide, classified in class 536, subclass 23.1 and class 435, subclass 320.1 and 325.
- II. Claims 22-26 and 32-36, drawn to an isolated polypeptide, classified in class 530, subclass 300.
- III. Claims 37-41, drawn to an antibody, classified in class 530, subclass 387.1.
- IV. Claims 42-53, drawn to a method for diagnosing Bardet-Biedl Syndrome (BBS), classified in class 435, subclass 440.
- V. Claims 54-62, drawn to a method for identifying genetic predisposition to disease, classified in class 436, subclass 512.
- VI. Claims 63-66, drawn to a method of screening for a modulator of the polypeptide, classified in class 530, subclass 330.
- VII. Claim 67, drawn to a promoter, classified in class 530, subclass 330.

The inventions are distinct, each from the other because of the following reasons:

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The inventions of groups I, II and III are patentably distinct from each other because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polynucleotide of group II is composed of amino acids linked together by peptide bonds and can assume complex tertiary structures. While the antibody of group III is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of groups I-III can be used in materially different processes, for example, the DNA of group I can be used in hybridization assays, the antibody of group III can be used in immunoassays, and the polypeptide of group II can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, II, and III are patentably distinct from each other.

The inventions of groups IV, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant application, the different inventions have different functions. The invention of group IV functions to diagnose Bardet-Biedl Syndrome. The invention of group V functions to identify genetic predisposition to disease. The invention of group VI functions to screen for a modulator. The invention of group VII functions as a promoter.

Upon election of an invention from groups I-VII above, applicant must further elect a patentably distinct sequence. **This is not an election of species.** Nucleotide sequences encoding

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different proteins are structurally distinct chemical compounds and are unrelated to one another.

Protein sequences are also structurally distinct compounds and are unrelated to one another.

These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide and protein sequence are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the prior invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because the restriction/election requirement is complex, a telephone call to applicant's attorney to request an oral election was not made. See MPEP 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed. See 37 CFR 1.143.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703)305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

RT
1654
9/22/03

RT



CHRISTOPHER R. TATE
PRIMARY EXAMINER